

# **Exhibit 10**

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 1999

Commission file number 1-9898  
Organogenesis Inc.  
(Exact name of registrant as specified in its charter)

Delaware 04-2871690  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification No.)

150 Dan Road, Canton, MA 02021  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (781) 575-0775

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, \$.01 value	American Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  
Yes ( X ) No ( )

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ( )

The approximate aggregate market value of voting stock held by non-affiliates of the registrant was \$442,900,000 based on the last reported sale price of the company's common stock on the American Stock Exchange as the close of business on March 3, 2000. There were 31,632,365 shares of common stock outstanding as of March 3, 2000, excluding treasury shares.

DOCUMENTS INCORPORATED BY REFERENCE

Document	Part of Form 10-K into which incorporated
Portions of the Registrant's Definitive Proxy Statement for its 2000 Annual Meeting of Stockholders .....	III

With the exception of the portions of the Definitive Proxy Statement for the registrant's 2000 Annual Meeting of Stockholders expressly incorporated into this Report by reference, such document shall not be deemed filed as a part of this Annual Report on Form 10-K.

## PART I

This Form 10-K contains forward-looking statements that involve risks and uncertainties. Forward-looking statements include information on:

- o Our business outlook and future financial performance;
- o Anticipated profitability, revenues, expenses and capital expenditures;
- o Future funding and expectations as to any future events; and
- o Other statements that are not historical fact and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties.

Although we believe that our plans, intentions and expectations reflected in or suggested by such forward-looking statements are reasonable, we can give no assurance that such plans, intentions or expectations will be achieved. When considering such forward-looking statements, you should keep in mind the risk factors and other cautionary statements in this Form 10-K. The risk and other factors noted throughout this Form 10-K could cause our actual results to differ materially from the results contained in any forward-looking statements.

## Item 1. Business

Organogenesis Inc. - a tissue engineering firm - designs, develops and manufactures medical products containing living cells and/or natural connective tissue. We are the developer and manufacturer of the only mass-manufactured medical product containing living human cells marketed in the US. Our product development program includes living tissue replacements, cell-based organ assist devices and other tissue-engineered products. Our lead product, Apligraf(R) skin construct, was launched in the US in June 1998 by marketer Novartis Pharmaceuticals Corporation. Our strategy is to commercialize products either by ourselves or through partners with an established marketing presence.

Organogenesis was organized as a Delaware corporation in 1985. Our principal offices are located at 150 Dan Road, Canton, Massachusetts 02021. The telephone number is 781/575-0775.

## Products

Organogenesis is utilizing its expertise in living mammalian (e.g., human) cells and connective tissue in its product development. In addition to Apligraf, major programs include VITRIX(TM) soft tissue replacement product, an off-the-shelf vascular graft and a liver assist device. These programs are profiled on the following pages.

Our portfolio also includes potential licensing opportunities. These opportunities include: GRAFTPATCH(TM) soft tissue reinforcement product, which has been cleared for marketing through the FDA 510k process; TESTSKIN(TM) II, an in vitro testing product; our conditioned medium, a cell culture product found to stimulate the generation of certain skin cell types; and our proprietary technology to produce collagen fibrils designed to provide local tissue bulking.

Apligraf(R) is a registered trademark of Novartis.

#### On the Market - Apligraf

**Product Description** - Like human skin, Apligraf has an organized, two-layered structure. It features the key components of skin - the lower dermal cells (fibroblasts), the upper epidermal cells (keratinocytes) and its key structural protein (collagen). Unlike human skin, Apligraf does not contain structures such as blood vessels, hair follicles and sweat glands or other cell types such as Langerhans' cells, melanocytes, macrophages or lymphocytes. Apligraf is mass-produced, available to physicians off-the-shelf and does not require hospitalization for use. To enable Apligraf to be used on any patient, cell types that might cause the product to be rejected are omitted from the manufactured product.

[Photo showing structure of Apligraf compared to Human Skin]

Under the microscope, as shown above, Apligraf has a structure similar to human skin.

**Status** - Apligraf is approved and marketed in the US for the treatment of venous leg ulcers. In December 1999, Organogenesis applied to the FDA for marketing approval for a second indication - diabetic foot ulcers. In fourth quarter 1999, Novartis began initial product introduction in Switzerland, the first of several planned in Europe. Apligraf is also marketed in Canada. Global Apligraf marketing rights belong to Novartis Pharma AG, which bears all sales and marketing costs for the product.

#### Current and Potential Markets -

**Chronic wounds:** Considered the largest potential market for Apligraf, chronic wounds can severely impact patient lives, causing pain, reduced mobility and lost work time. Wounds can lead to serious infection, hospitalization and, in some cases, amputation. They can also be quite costly to the medical system.

**Venous leg ulcers:** Apligraf is approved and marketed in the US for the treatment of venous leg ulcers, a type of chronic wound caused by poor blood circulation. Venous leg ulcers are estimated to afflict approximately 1,000,000 people in the US alone. Many of these wounds resist healing with traditional treatments and may be candidates for Apligraf therapy.

**Diabetic foot ulcers:** Diabetic foot ulcers, another chronic wound type, affect up to 800,000 people in the US. A leading cause of hospitalization among diabetics, they can lead to amputation: over 50,000 amputations are performed on diabetics each year in the US. In December 1999, we submitted to the FDA an Apligraf PMA supplement for approval for use in diabetic foot ulcers. The basis of the PMA supplement is the Apligraf diabetic ulcer pivotal trial. In this multi-center trial, Apligraf was found to heal more patients, faster, than standard care alone.

**Acute wounds:** Serious acute wounds, such as those caused by burns or severe skin disorders, tend to be less common than chronic wounds: in the US, fewer than 15,000 people yearly are burned sufficiently to require skin grafting. However, they can affect a large percentage of the body. Better treatments are needed to improve patient outcome from such wounds. For burns and other acute wounds, such as skin surgery wounds, there is also a need to improve the quality of healing, such as reducing scarring. We currently have underway a pivotal trial designed to assess whether use of Apligraf to treat wounds due to skin cancer surgery leads to a better cosmetic outcome.

Data from smaller Apligraf studies, including in donor site wounds, burns and epidermolysis bullosa (a genetic skin disorder), were published or presented during 1999 by the Company or by practicing physicians.

#### In Pilot Human Clinical Trials - VITRIX(TM)

The impetus for VITRIX development was the need for better treatments, for damaged dermal and other connective tissues. For example, the body does not regenerate dermal tissue - skin's lower layer -when it is lost due to injury or surgery. Without dermal tissue to guide the repair process, humans heal with scar tissue. Dermal tissue is also important from a practical perspective: wounds healing over inadequate dermal tissue can have a sunken or puckered appearance. Other internal connective tissues can also become damaged or destroyed. These include structural parts of the spine and soft tissue lost with tumor removal.

VITRIX is composed of the key components of human dermal tissue - dermal cells (fibroblasts) and dermal proteins (collagen and other matrix molecules) - in an all-natural tissue. Potential uses for VITRIX include in wound repair, as well as in orthopedic, general and reconstructive surgery. Organogenesis began pilot human clinical trials with VITRIX in 1999.

#### Research and Development Programs

##### Vascular Graft

Each year in the United States, approximately 375,000 coronary artery bypass graft (CABG) procedures are performed to restore blood flow in the arteries that keep the heart alive. Each CABG may require several by-pass grafts as patients may have multiple blockages. Today, surgeons rely on vein harvested from the patient for graft material. Use of patient vein, however, has its drawbacks. The patient may not have sufficient healthy vein available. Harvesting vein can greatly extend the duration and, thus, cost of the procedure. It also creates a second wound site, increasing patient discomfort and risk of complications.

We are developing an off-the-shelf vascular graft designed to provide the necessary physical properties while becoming converted into living tissue through population with the patient's own cells. Animal data on this program, published in the scientific journal, Nature Biotechnology, in November 1999, showed that our non-living vascular graft had been converted to living tissue within 90 days of implantation. Our vascular graft is currently in animal studies.

##### Liver Assist Device

Today in the United States, approximately 150,000 people yearly are hospitalized for liver disease and over 43,000 people die from it. Liver transplantation, currently the only effective treatment for liver failure, has a number of drawbacks, including limited organ availability, riskiness, invasiveness and high cost. Patients with acute liver failure risk dying before a donor liver becomes available, creating a need for a bridge to transplant. A liver assist device is also expected to enable some patients to avoid transplantation by providing liver function until their own liver regenerates.

Organogenesis has a research program to develop a device that will house living liver cells to process patient blood, providing temporary liver function using a dialysis-type procedure. We are applying our expertise in cell procurement, culture and optimization to this program. In 1999, Organogenesis acquired intellectual property and equipment from Baxter Healthcare Corporation related to device design and manufacturing.

Our liver assist device program is currently in research. In October 1999, the program was selected for a \$2 million award under the Advanced Technology Program of the National Institute for Standards and Technology. This two-year grant is to assist Organogenesis in designing an effective device prototype.

#### Risk factors

##### Our Company Has a History of Losses and We Expect to Continue to Incur Losses

Organogenesis Inc. was founded in 1985. We have incurred operating losses in every year of our existence. We incurred net losses of \$19,807,000 for the year ended December 31, 1997, \$14,031,000 for the year ended December 31, 1998 and \$28,350,000 for the year ended December 31, 1999, which losses are continuing. As of December 31, 1999, we have an accumulated deficit of \$129,367,000. We have not achieved profitability and expect to continue to incur net losses. The extent of future losses and the time required to achieve profitability is highly uncertain. Moreover, although our business is not seasonal in nature, our revenues tend to vary significantly from fiscal quarter to fiscal quarter.

##### In Order to Achieve Commercial Success, Our Products Must Gain Market Acceptance

We manufacture and market one principal product: Apligraf. We have only recently begun to market Apligraf, which is marketed through Novartis, and to generate revenues from the commercialization of this product. Products under development will require additional research and development efforts, including clinical testing and regulatory approval, prior to commercial use. Our potential products are subject to the risks of failure inherent in the development of medical products based on new technologies. These risks include the possibilities that:

- o Our approach will not be successful;
- o Our potential products will be found to be unsafe, ineffective or otherwise will fail to meet applicable regulatory standards or receive necessary regulatory clearances;
- o The potential products, if safe and effective, will be difficult to develop into commercially-viable products, will be difficult to manufacture on a large scale, will be uneconomical to market, will fail or be delayed in gaining acceptable insurance reimbursement or will fail to obtain acceptance by the medical community;
- o Proprietary rights of third parties will preclude us from marketing such products; or
- o Third parties will market superior or equivalent products.

Our business results would be hurt if we are unable to demonstrate to the medical community the efficacy, relative safety and cost effectiveness of treating patients with our products or if our products were not accepted as alternatives to other existing or new therapies.

### Our Markets Are Competitive and Our Competitors Could Develop More Effective Products

We are engaged in the rapidly evolving and competitive field of tissue engineering for the treatment of skin wounds and other medical needs. Our competitors include tissue engineering companies, xenotransplant companies, wound care divisions of major pharmaceutical companies and other pharmaceutical, biotechnology and medical products companies using traditional technologies to develop products for wound care. Some of these companies have much greater resources, research and development staffs and facilities, experience in conducting clinical trials and obtaining regulatory approvals and experience in the manufacturing, marketing and distribution of products than we do. Our competitive position is based upon our ability to:

- o create and maintain scientifically-advanced technology and proprietary products and processes;
- o attract and retain qualified personnel;
- o obtain patent or other protection for our products and processes;
- o obtain required government approvals on a timely basis;
- o manufacture products on a cost-effective basis; and
- o successfully market products.

If we are not successful in meeting these goals, our business could be hurt. Similarly, our competitors may succeed in developing technologies, products or procedures that are more effective than any that we are developing or that would render our technology and products obsolete, noncompetitive or uneconomical.

### We Currently Depend Upon Strategic Relationships to Market Our Products and Our Distributors May Not Be Successful in Marketing Our Products

We currently have limited experience in sales, marketing and distribution and may need to develop long-term strategic relationships with partners, such as Novartis, that have marketing and sales forces with technical expertise and distribution capability. To the extent that we enter into such relationships, our revenues will depend upon the efforts of third parties who may or may not be successful. We may not be able to establish or maintain long-term strategic relationships, and if we do, our collaborators may not be successful in gaining market acceptance for our products. To the extent that we choose not to or are unable to negotiate or maintain collaborations, we may need more capital and resources to undertake a commercialization program at our own expense. In addition, we may encounter significant delays in introducing our products into certain markets or find that the commercialization of products in such markets may be adversely affected by the absence of collaborative agreements. We are dependent on Novartis for the successful marketing and selling of Apligraf worldwide. If Novartis does not succeed in marketing and selling Apligraf or gaining international approvals for the product or if we are unable to meet the production demand of global commercialization, our operating results will suffer.



Our Ability to Commercialize Our Products Depends Upon Our Compliance with Government Regulations

Our present and proposed activities are subject to extensive and rigorous regulation by governmental authorities in the US and other countries. To clinically test, produce and market medical devices for human use, we must satisfy mandatory procedural and safety and efficacy requirements established by the FDA and comparable state and foreign regulatory agencies. Typically, such rules require that products be approved by the government agency as safe and effective for their intended use prior to being marketed. The approval process is expensive, time consuming and subject to unanticipated delays. Our product candidates may not be approved. In addition, our product approvals could be withdrawn for failure to comply with regulatory standards or due to unforeseen problems after the product's marketing approval.

Testing is necessary to determine safety and efficacy before a submission may be filed with the FDA to obtain authorization to market regulated products. In addition, the FDA imposes various requirements on manufacturers and sellers of products under its jurisdiction, such as labeling, Good Manufacturing Practices, record keeping and reporting requirements. The FDA also may require post-marketing testing and surveillance programs to monitor a product's effects. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals or could negatively affect the marketing of our existing products. We would not be able to commercialize our products as planned and our operating results would be hurt if:

- o the regulatory agencies find our testing protocols to be inadequate;
- o the appropriate authorizations are not granted on a timely basis, or at all;
- o the process to obtain authorization takes longer than expected or we have insufficient funds to pursue such approvals;
- o we lose previously-received authorizations; or
- o we do not comply with regulatory requirements.

Medical and biopharmaceutical research and development involves the controlled use of hazardous materials, such as radioactive compounds and chemical solvents. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and waste products. In addition, we handle and dispose of human tissue. Although we believe that our safety procedures for handling these materials are adequate, if accidental contamination or injury were to occur, we could be liable for damages.

We Rely Heavily Upon Our Patents and Proprietary Technology and Any Future Claims that Our Patents Are Invalid Could Seriously Harm Our Business

We rely upon our portfolio of patent rights, patent applications and exclusive licenses to patents and patent applications relating to living tissue products, organ assist treatments and other aspects of tissue engineering. We currently have 24 patents issued in the US, 11 pan-European patents issued and six patents issued in Japan. As part of our continuing interest in protecting intellectual property rights, we have filed and are prosecuting 16 other patent applications in the US. We also license some of our technologies under an exclusive patent license agreement with the Massachusetts Institute of Technology. The agreement with MIT covers certain US patents and corresponding patents in Europe and Japan. The earliest patent expiration is in 2006. Pursuant to the MIT agreement, we have been granted an exclusive, worldwide license to make, use and sell the products covered by the patents and to practice the procedures covered by the patents. We are not currently a party in any infringement claim.



We expect to aggressively patent and protect our proprietary technologies. However, we cannot be sure that any additional patents will be issued to us as a result of our domestic or foreign patent applications or that any of our patents will withstand challenges by others. Patents issued to or licensed by us may be infringed or third parties may independently develop either the same or similar technology. Similarly, our patents may not provide us with meaningful protection from competitors, including those who may pursue patents which may prevent, limit or interfere with our products or will require licensing and the payment of significant fees or royalties by us to such third parties in order to enable us to conduct our business. We may sue or be sued by third parties regarding patents and other intellectual property rights. These suits are costly and would divert funds and management and technical resources from our operations.

We also rely upon unpatented proprietary technology, know-how and trade secrets and seek to protect them through confidentiality agreements with employees, consultants and advisors. We request that any corporate sponsor with which we enter into a collaborative agreement do so as well. If these confidentiality agreements are breached, we may not have adequate remedies for the breach. In addition, others may independently develop or otherwise acquire substantially the same proprietary technology as our technology and trade secrets.

We have relationships with a number of academic consultants who are not employed by us. Accordingly, we have limited control over their activities and can expect only limited amounts of their time to be dedicated to our activities. These persons may have consulting, employment or advisory arrangements with other entities that may conflict with or compete with their obligations to us. Our consultants typically sign agreements that provide for confidentiality of our proprietary information and results of studies. However, in connection with every relationship, we may not be able to maintain the confidentiality of our technology, the dissemination of which could hurt our competitive position and results of operations. To the extent that our scientific consultants develop inventions or processes independently that may be applicable to our proposed products, disputes may arise as to the ownership of the proprietary rights to such information, and we may not win those disputes.

#### We Must Be Able to Manufacture Our Products Successfully

The process of manufacturing our products is complex, requiring strict adherence to manufacturing protocols. We have been producing our lead product, Apligraf, for commercial sale since the second half of 1997 in adherence with these manufacturing protocols. However, with increasing demand for Apligraf, we must further transition from small-scale to full-scale production of our products. If we do not make the full transition successfully, we will not be able to satisfy the demands for our products and our results of operations will be hurt.

We are required to maintain a manufacturing facility in compliance with Good Manufacturing Practices. Manufacturing facilities and processes pass an inspection before the FDA issues any product licenses necessary to market medical therapeutics and are subject to continual review and periodic inspection. We may not be able to maintain the necessary regulatory approvals for our manufacturing operations or manufacture our products in a cost-effective manner. If we were unable to manufacture potential products independently or obtain or retain third party manufacturing on commercially-acceptable terms, the submission of products for final regulatory approval and initiation of marketing would be delayed. This, in turn, may cause us to be unable to commercialize product candidates as planned, on a timely basis or on a profitable basis.

#### We Must Be Able to Obtain Adequate Sources of Supply

We manufacture Apligraf for commercial sale, as well as for use in clinical trials, at our Canton, Massachusetts facility. Among the fundamental raw materials needed to manufacture Apligraf are keratinocyte and fibroblast cells. Because these cells are derived from donated infant foreskin, they may contain human-borne pathogens. We perform extensive testing of the cells for pathogens, including the HIV or "AIDS" virus. Our inability to obtain cells of adequate purity, or cells that are pathogen-free, would limit our ability to manufacture sufficient quantities of our products.

Another major material required to produce our products is collagen, a protein obtained from animal source tissue. We have developed a proprietary method of procuring our own collagen that we believe is superior in quality and strength to collagen available from commercial sources. We currently obtain animal source tissue from US suppliers only. We may not be able to obtain adequate supplies of animal source tissue to meet our future needs or on a cost-effective basis. The thermo-formed tray assembly that is used in the manufacturing process of Apligraf is available to us under a supply arrangement with only one manufacturing source. Because the FDA approval process requires manufacturers to specify their proposed materials of certain components in their applications, FDA approval of a new material would be required if a currently approved material became unavailable from a supplier. If we are unable to obtain adequate supplies of thermo-formed tray assemblies to meet future Apligraf manufacturing needs or if we cannot obtain such assemblies on a cost-effective basis, our operations would be hurt.

Interruptions in our supply of materials may occur in the future or we may have to obtain substitute vendors for these materials. Any significant supply interruption would adversely affect the production of Apligraf. In addition, an uncorrected impurity or a supplier's variation in a raw material, either unknown to us or incompatible with our manufacturing process, could hurt our ability to manufacture products.

#### The Retention of Key Personnel Is Important to Our Competitive Position

Because of the specialized nature of our business, our success will depend upon our ability to attract and retain highly qualified personnel and to develop and maintain relationships with leading research institutions. The competition for those relationships and for experienced personnel amongst the biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions is intense. If we are unable to continue to attract and retain such personnel or relationships, our competitive position could be hurt.

#### We May Be Subject to Product Liability Suits; Our Insurance May Not Be Sufficient to Cover Damages

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and sale of medical products. The use of our products and product candidates, whether for clinical trials or commercial sale, may expose us to product liability claims or product recall and possible adverse publicity. Although we have product liability insurance coverage, the level or breadth of our coverage may not be adequate to fully cover potential liability claims. In addition, we may not be able to obtain additional product liability coverage in the future at an acceptable cost. A successful claim or series of claims brought against us in excess of our insurance coverage and the effect of product liability litigation upon the reputation and marketability of our technology and products, together with the diversion of the attention of key personnel, could negatively affect our business.

Our Business Is Subject to the Uncertainty of Third-Party Reimbursement  
and Health Care Reform Measures Which May Limit Market Acceptance

In both domestic and foreign markets, our ability to commercialize our product candidates will depend, in part, upon the availability of reimbursement from third-party payors, such as government health administration authorities, private health insurers and other organizations. Third-party payors are increasingly challenging the price and cost-effectiveness of medical products. If our products are not considered cost-effective, third-party payors may limit reimbursement. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA and by refusing, in some cases, to provide any coverage for uses of approved products for disease indications for which the FDA has not granted marketing approval. If government and third party payors do not provide adequate coverage and reimbursement levels for uses of our products, the market acceptance of our products would be limited.

There have been a number of federal and state proposals during the last few years to subject the pricing of pharmaceuticals to government control and to make other changes to the health care system of the US. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payors for health care goods and services may take in response to any health care reform proposals or legislation. We cannot predict the effect health care reforms may have on our business.

Our Stock Price Is Volatile and Can Fluctuate Significantly Based on  
Events Not In Our Control and General Industry Conditions

The biotechnology sector seems particularly vulnerable to abrupt changes in investor sentiment. Stock prices of companies in the biotechnology industry, including ours, can swing dramatically, with little relationship to operating performance. Our stock price may be affected by a number of factors including, but not limited to:

- o clinical trial results and other product development events;
- o the outcome of litigation;
- o decisions relating to intellectual property rights;
- o the entrance of competitive products into our market;
- o changes in reimbursement policies or other practices related to the pharmaceutical industry; or
- o other industry and market changes or trends.

During the past three years, the price of our common stock, adjusted for stock splits, has ranged from \$6.75 to \$35.19 per share. These fluctuations can occur due to events outside of our control, regulatory actions such as government approval of products or reimbursements, and general market conditions affecting the biotechnology sector or the stock market generally.

We will Need to Raise Additional Funds, Your Investment Could Be Adversely  
Affected

Based upon our current plans, we believe that common stock issued subsequent to December 31, 1999, together with existing working capital and future funds from Novartis, including product and royalty revenue, will be sufficient to finance operations into 2001. However, this statement is forward-looking and changes may occur that would significantly decrease available cash before such time. Factors that may change our cash requirements include:

- o Delays in obtaining regulatory approvals of products in different countries, if needed, and subsequent timing of product launches;
- o Delays in commercial acceptance and reimbursement when product launches occur;
- o Changes in the progress of research and development programs; and
- o Changes in the resources devoted to outside research collaborations or projects, self-funded projects, proprietary manufacturing methods and advanced technologies.

Any of these events could adversely impact our capital resources, requiring us to raise additional funds. Management believes that additional funds may be available through equity or debt financing, strategic alliances with corporate partners, capital lease arrangements, or other sources of financing in the future. There can be no assurances that these funds will be available when required on terms acceptable to us, if at all. If adequate funds are not available when needed, we would need to delay, scale back or eliminate certain research and development programs or license to third parties certain products or technologies that we would otherwise undertake ourselves, resulting in a potential material adverse effect on our financial condition and results of operations.

#### Our Anti-Takeover Measures May Affect the Value of Our Stock

We, as a Delaware corporation, are subject to the General Corporation Law of the State of Delaware, including Section 203, an anti-takeover law enacted in 1988. In general, Section 203 restricts the ability of a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder. As a result of the application of Section 203 and certain provisions in our certificate of incorporation and bylaws, potential acquirors may be discouraged from attempting to acquire us, thereby possibly depriving our stockholders of acquisition opportunities to sell or otherwise dispose of our stock at above-market prices typical of such acquisitions.

We have also adopted a shareholder rights plan, which gives holders of common stock the right to purchase shares of our Series B Junior Participating Preferred Stock if a potential acquiror purchases or plans to make a tender offer to purchase 15% or more of our outstanding common stock. The existence of this plan may make it more difficult for a third party to acquire control of us.

We are authorized to issue up to 1,000,000 shares of preferred stock, \$1.00 par value per share and to determine the price, privileges and other terms of such shares. The issuance of any preferred stock with superior rights to the common stocks could reduce the value of the common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with or sell our assets to a third party, thereby preserving control of Organogenesis by present owners and management and preventing our holders of common stock from realizing a premium on their shares.

#### The Value Of Your Securities May Decrease If Other Security Holders Exercise Their Options and Warrants or Convert Their Debt Into Common Stock or If Other Stockholders Sell Their Stock

At December 31, 1999, 30,604,019 shares of our common stock are outstanding (excluding 85,000 treasury shares). We have reserved an additional 12,718,286 shares of common stock for future issuance upon exercise or conversion of options, warrants, the Series C convertible preferred stock and the convertible debentures (excluding 3,000,000 shares of common stock reserved under a shelf registration declared effective on February 14, 2000). We plan to issue additional options and warrants in the future. If any of these securities are exercised or converted, investors may experience significant dilution in the market value and earnings per share of the common stock into which these securities are convertible.

#### We Have No Intention to Pay Cash Dividends

We have never paid any cash dividends on our common stock. We currently intend to retain all future earnings, if any, for use in our business and do not expect to pay any cash dividends in the foreseeable future. As a result, an investor will only recognize an economic gain on an investment in our stock from an appreciation in the price of our stock.

#### Collaborative and Other Agreements

In January 1996, we entered into an agreement with Novartis Pharma AG granting them exclusive global marketing rights to Apligraf. Under the agreement, Novartis is responsible for Apligraf sales and marketing costs worldwide, as well as all clinical trials, registrations and patent costs outside the US. The agreement provides us with up to \$40,000,000 in equity investments and nonrefundable research, development and milestone support payments. The equity investments made were determined using quoted market prices over a 30-day period or a premium to market, as in accordance with the contract terms. The nonrefundable research, development and milestone support payments were recognized as "Research and development support from related party" revenue in the year received. All payments received relate to research and development efforts that had been completed and no future obligations exist relating to these payments. The table below summarizes all payments received and the year they were recorded:

	1996	1997	1998	1999
	-----	-----	-----	-----
Equity investments	\$5,000,000	\$ --	\$ 6,000,000	\$ --
Research and development support from related party	6,500,000	2,500,000	6,750,000	--
	-----	-----	-----	-----
Total	\$11,500,00	\$2,500,000	\$12,750,000	\$ --
	=====	=====	=====	=====

The remaining payments are based upon achievement of specified events. During March 2000, we received \$5,000,000 from Novartis, which represents a milestone support payment received in advance of achievement of the milestone. Under the agreement, we supply Novartis' global requirements for Apligraf and receive revenue consisting of a per unit manufacturing payment and royalty on net product sales.

During the first quarter of 1999, Novartis agreed to provide funding for certain programs to be conducted by Organogenesis. We have recorded \$572,000 for the period ended December 31, 1999 relating to the initiation of these programs, which is included in "Other income".

In 1994, we signed a license agreement with Toyobo Ltd. granting Toyobo a license to manufacture and market TESTSKIN(TM) in Japan in exchange for royalty payments. Additionally, Toyobo may, but is not obligated to, purchase collagen and other products from us. Revenues under this arrangement are included in other income. This agreement is coterminous with certain patents.

#### Research Agreements

We have entered into various collaborative research agreements that are generally funded over a one or two-year period. Each agreement is reviewed at least annually and the amounts to be funded for the next period are then determined. Either party may cancel the agreement upon advance written notice. Total payments under these agreements were \$571,000, \$648,000 and \$662,000 for 1997, 1998 and 1999, respectively. All our research agreements are early stage today, but have the potential to develop into more material relationships in the future.



## Research and Development

We plan to continue to focus product development efforts on high-quality cell therapy, connective tissue and other types of tissue-engineered products for a variety of areas, including wound care, surgery, cardiovascular medicine and liver disease.

Our research and development staff consists of scientists and laboratory assistants with technical backgrounds in cell biology, matrix biology, cell culture, immunology, cryopreservation, molecular biology and clinical medicine.

For 1997, 1998 and 1999, research and development expenses were \$13,854,000, \$17,542,000, and \$18,166,000, respectively, which include production costs (except cost of product sales commencing in 1999) and funding of the research and other agreements noted above. All amounts expended were for company-sponsored research and development.

## Employees

As of March 24, 2000, we had 205 full-time employees. We have established a stock option plan providing equity incentives, an employee stock purchase plan and a 401(k) plan for all full-time employees. We believe that, through equity participation, attractive fringe benefit programs and the opportunity to contribute to the development and commercialization of new products using new technology, we will continue to be able to attract highly-qualified personnel.

## Scientific Advisory Board

We have a Scientific Advisory Board ("SAB") composed of five physicians, professors and scientists in various fields of medicine and science. The SAB meets from time to time to advise and consult with management and our scientific staff. Each member of the SAB is expected to devote only a portion of his time to us and may have consulting or other advisory arrangements with other entities that may conflict or compete with his obligations to us. Members of the SAB have no formal duties, authority or management obligations.

## Item 2. PROPERTIES

We occupy our main offices and manufacturing premises under a facility lease for 79,500 square feet of space in Canton, Massachusetts at an annual average base rent of approximately \$790,000, plus operating expenses, that expires on September 30, 2004. This lease has three options to extend the term for an additional five years per option. Taxes, insurance and operating expenses are our responsibility under the terms of the lease. In May 1999, we entered into another facility lease for approximately 62,500 square feet of additional office and warehouse space in Canton, Massachusetts at an annual average base rent of approximately \$421,875, plus operating expenses, that expires on December 5, 2004. This lease has three options to extend the term for an additional five years per option. In total, we currently lease approximately 142,000 square feet of space. We also had a facility lease for warehouse and office space that expired on December 31, 1999. In January 1999, we entered into a noncancelable operating lease for certain office equipment.

We believe that current facilities will adequately support manufacturing needs and research and development activities through the end of 2000 and beyond.



Item 3. LEGAL PROCEEDINGS

None

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None

## PART II

## Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the American Stock Exchange under the symbol ORG. On March 3, 2000, there were 763 shareholders of record of our common stock. The table below lists the high and low quarterly range of reported closing prices of our common stock during the past two years.

	1998		1999	
	High	Low	High	Low
First Quarter	\$ 27 3/16	\$ 15 9/16	\$ 15 11/16	\$ 10 15/16
Second Quarter	35 3/16	19 5/8	13 3/4	8 3/4
Third Quarter	18 15/16	8 7/8	11 9/16	7 1/2
Fourth Quarter	16 3/8	9 3/16	11 7/8	6 3/4

The amounts above have been adjusted to reflect a one-for-four stock split accounted for as a stock dividend distributed on April 29, 1998 to stockholders of record as of April 22, 1998. All related data in the consolidated financial statements reflect this stock dividend for all periods presented, except for the Statements of Changes in Stockholders' Equity. No cash dividends have been paid to date on our common stock and we do not anticipate paying cash dividends in the foreseeable future.

## Item 6. SELECTED FINANCIAL DATA (in thousands, except share data and number of employees)

	For the Years Ended December 31,				
	1995	1996	1997	1998	1999
Revenues	\$ 627	\$ 7,527	\$ 3,531	\$ 8,997	\$ 3,578
Net Loss	(12,737)	(7,499)	(19,807)	(14,031)	(28,350)
Net Loss Per Common Share	(0.52)	(0.27)	(0.70)	(0.48)	(0.93)
Working Capital	12,886	11,256	4,843	15,541	2,981
Capital Expenditures	319	3,311	1,069	2,464	5,767
Total Assets	19,304	22,436	13,780	26,710	27,305
Total Long-Term Debt	--	--	--	--	22,287
Stockholders' Equity (Deficit)	17,798	18,478	11,523	23,239	(6,974)
Number of Employees	97	115	137	186	208

## Item 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

In Management's Discussion and Analysis, we explain the general financial condition and results of operations for Organogenesis Inc. As you read this MD&A, referring to our consolidated financial statements that follow may be helpful. Further information on the Company, our lead product and our pipeline is contained in the "Business" section of this Form 10-K.

### Overview of Organogenesis Inc.

Organogenesis Inc. - a tissue engineering firm - designs, develops and manufactures medical products containing living cells and/or natural connective tissue. We are the developer and manufacturer of the only mass-manufactured medical product containing living human cells marketed in the US. Our product development program includes living tissue replacements, cell-based organ assist devices and other tissue-engineered products. Our lead product, Apligraf(R) skin construct, was launched in the US in June 1998 by marketer Novartis Pharmaceuticals Corporation. Our strategy is to commercialize products either by ourselves or through partners with an established marketing presence.

### Our Lead Product, Apligraf

Apligraf is approved and marketed in the US for the treatment of venous leg ulcers. In December 1999, Organogenesis applied to the FDA for marketing approval for a second indication - diabetic foot ulcers. Novartis Pharma AG has global Apligraf marketing rights. In fourth quarter 1999, Novartis began initial product introduction in Switzerland, the first of several planned in Europe. Novartis also markets Apligraf in Canada.

A pivotal trial is underway designed to assess whether use of Apligraf to treat wounds due to skin cancer surgery leads to a better cosmetic outcome. Data from smaller Apligraf studies, including in donor site wounds, burns and epidermolysis bullosa (a genetic skin disorder), were published or presented during 1999.

### Our Pipeline

Our pipeline includes VITRIX soft tissue replacement product, now in pilot human clinical trials; our vascular graft program, currently in animal studies; and our liver assist device program, currently in research. Our portfolio also includes potential licensing opportunities. These opportunities include: GraftPatch(TM) soft tissue reinforcement product, which has been cleared for marketing through the FDA 510k process; TESTSKIN(TM) II, an in vitro testing product; our conditioned medium, a cell culture product found to stimulate the generation of certain skin cell types; and our proprietary technology to produce collagen fibrils designed to provide local tissue bulking.

### Results of Operations

With the approval and launch of Apligraf, we began a new era of operations. We are seeing, as expected, a gradual ramp-up in sales. We expect production costs to exceed product sales for the near term due to start-up expenses and the high costs associated with low volume production. However, we expect production volume to increase.

## Revenue

Total revenues for years 1997, 1998 and 1999 consisted of:

	1997	1998	1999
R&D support from related party	\$2,500,000	\$6,750,000	\$ --
Product sales to related party and others	444,000	1,082,000	1,844,000
Other income	85,000	107,000	832,000
Interest income	502,000	1,058,000	902,000
	\$3,531,000	\$8,997,000	\$3,578,000
	=====	=====	=====

The year-over-year increase in product sales to related party and others is due to increased unit sales of Apligraf to Novartis. We expect Apligraf commercial sales to continue to increase. Product sales to others are insignificant in 1999 and 1998, and are approximately \$205,000 in 1997. The increase in other income is mainly due to Novartis funding of certain programs. R&D support payments are recognized when earned and are nonrefundable. The year-over-year changes in interest income are primarily due to the difference in funds available for investment.

## Expenses

Cost of product sales: Our cost of product sales was \$3,773,000 in 1999. All costs of production prior to 1999 were included in research and development expenses due to insignificant commercial sales and low production volume associated with early stage commercial launch. Cost of product sales includes the direct costs to manufacture and package Apligraf and an allocation of our production related indirect costs. Cost of product sales exceeded product sales due to the start-up costs of new product introduction and the high costs associated with low volume production. We expect production volume to increase and our margins to improve. We expect to continue to expand production operations during the next 12 months.

Research and development: Our R&D and operations expenses consist of costs associated with research, development, clinical and operations (excluding cost of sales in 1999). These expenses increased to \$18,166,000 for 1999, from \$17,542,000 in 1998 and \$13,854,000 in 1997. The increase in 1999 was primarily due to: approximately \$1,483,000 in personnel costs, outside services, supplies, and occupancy costs to support our ongoing programs, including VITRIX and liver assist device, as well as costs to support publications studies and other sponsored programs; offset by an approximate \$596,000 net decrease in clinical related costs as last year included non-recurring expenses related to FDA approval and the Apligraf diabetic ulcer pivotal trial was at its peak; and offset by an approximate \$327,000 net decrease in operating related expenditures. The increase in 1998, which included cost of product sales on insignificant commercial sales and low volume production, was primarily due to the following: approximately \$881,000 clinical trials activity, including the Apligraf diabetic ulcer pivotal trial and non-recurring expenses related to FDA approval; approximately \$1,093,000 for progressing preclinical programs, including VITRIX; and approximately \$1,597,000 relating to investing in manufacturing operations, including personnel additions. We expect to continue to advance the product pipeline during the next 12 months.

General and administrative expenses: Our G&A expenses include the costs of our corporate, finance, information technology and human resource functions. G&A expenses increased to \$7,808,000 for 1999 from \$5,486,000 in 1998 and \$3,929,000 in 1997. The 1999 increase is primarily due to: approximately \$1,304,000 for personnel additions and increased outside and professional fees; approximately \$565,000 relating to occupancy costs and consolidating administrative facilities; and approximately \$411,000 for the estimated fair value of warrants issued relating to a consulting contract. The 1998 increase of \$1,557,000 is primarily due to adding support staff and higher outside and professional services, partially relating to regulatory-related activities. We expect the growth in G&A expenses to increase at a slower rate.

Other costs and expenses: Included in costs and expenses for 1999 is a non-cash charge of \$900,000 relating to the purchase of incomplete technology to be used specifically in our liver assist device research and development efforts (refer to the commitments footnote to the Financial Statements for a full description of this technology). The purchase was made to strengthen our resources to develop the technology. The charge to expense was due to the early stage of the technology that has not provided proof of principle. Additionally, the time and cost to prove this principle is not known. This program is expected to be a long-term endeavor that will be evaluated periodically to determine future spending levels. It is expected that development of a liver assist device will cost millions of dollars and take 8 to 10 years before we could develop a product, which might be approved for commercial sale. We do not currently have the resources to fully develop such a product. It is our intent that once proof of principle is established, we will seek funding or partnership for the project.

Additionally, in May 1997, we incurred a one-time, non-cash compensation charge of \$5,555,000 relating to the extension of the term of a stock option held by an officer. Interest expense was \$1,281,000 for 1999 due to the issuance of convertible debentures in March 1999.

#### Net Income

We incurred a net loss of \$28,350,000, or \$.93 per share (basic and diluted) for 1999, compared to a net loss of \$14,031,000, or \$.48 per share (basic and diluted) for 1998 and a net loss of \$19,807,000, including the \$5,555,000 non-cash charge, or \$.70 per share (basic and diluted) for 1997. We may incur additional losses as expenditures continue to increase due to expansion of operations and research programs.

For 1997, the net loss per common share (basic and diluted) and weighted average number of common shares outstanding were adjusted for a one-for-four stock split accounted for as a stock dividend distributed on April 29, 1998. After accounting for the one-for-four stock split, the 1997 net loss per common share (basic and diluted) decreased to \$.70 per share as compared to \$.87 per share.

#### Capital Resources and Liquidity

##### Funds Used in Operations

At December 31, 1999, we had cash, cash equivalents and investments in the aggregate amount of \$12,439,000 and working capital of \$2,981,000 compared to \$17,841,000 and \$15,541,000, respectively, at December 31, 1998. Cash equivalents consist of money market funds, which are highly liquid and have original maturities of less than three months. Investments consist of marketable securities that have an A or A1 rating or better with a maximum maturity of two years. Cash used in operating activities was \$23,650,000 in 1999 and \$11,587,000 in 1998, primarily for financing our ongoing research, development and manufacturing operations.

### Capital Spending

Capital expenditures were \$5,767,000 and \$2,464,000 during 1999 and 1998, respectively, primarily related to further build-out of the current facility to support Apligraf manufacturing, as well as the acquisition of equipment for research and development programs and manufacturing. We will continue to utilize funds during 2000 to expand our current facility in the areas of Apligraf manufacturing, quality systems labs and packaging.

### Novartis Support

The collaborative agreement with Novartis provides us with up to \$40,000,000 in equity investments and nonrefundable research, development and milestone support payments, of which \$0 was received during 1999, \$12,750,000 in 1998, and \$2,500,000 in 1997, all of which are non refundable. The remaining payments are based upon achievement of specified events. During March 2000, we received \$5,000,000 from Novartis, which represents a milestone support payment received in advance of achievement of the milestone. Under the agreement, we supply Novartis' global requirements for Apligraf and receive revenue consisting of a per unit manufacturing payment and royalties on product sales.

### Financing

From inception, we have financed our operations substantially through private and public placements of equity securities, as well as receipt of research support and contract revenues, interest income from investments, sale of products and receipt of royalties. During 1999, financing activities provided additional cash and working capital of approximately \$24,015,000 primarily from: the sale of five-year convertible debentures and warrants to purchase common stock that generated net proceeds of \$19,425,000; the issuance of a term loan that generated proceeds of \$4,728,000 and the exercise of stock options of \$813,000, offset by the purchase of treasury stock totaling \$951,000. Financing activities provided cash of approximately \$25,747,000 during 1998 from: the sale of 200 shares of Series C convertible preferred stock that generated net proceeds of approximately \$19,117,000; an equity investment of \$6,000,000 from Novartis; and the exercise of stock options of \$1,021,000, partially offset by the purchase of treasury stock totaling \$391,000. The repurchased stock will provide us with treasury shares for general corporate purposes.

During March 2000, we redeemed in cash all outstanding shares of Series C convertible preferred stock for approximately \$6,180,000. At December 31, 1999, we had approximately 62 shares of Series C convertible preferred stock outstanding. In the event that any Series C preferred stock are outstanding on the mandatory conversion date of March 26, 2000, we have the option of redeeming any such outstanding Series C preferred stock by: (1) paying cash equal to the product of the number of Series C preferred stock outstanding multiplied by the stated value of \$100,000 per share; (2) issuing common stock equal to 1.15 of the stated value divided by the average of the closing bid prices for the 20 consecutive trading days prior to the mandatory conversion date; or (3) any combination of these methods.



On March 31, 1999, we completed a financing of \$20,000,000 through the private placement of five-year convertible debentures and 400,000 warrants to purchase common stock. The debentures are convertible at a fixed price of \$14.50 per share at any time on or after March 30, 2000. Interest on the debentures accrues at 7% annually, payable in cash, common stock (at the average trading price for the twenty trading days preceding the due date) or any combination thereof, at our option, semi-annually on September 30 and March 31 or on the date any of the principal outstanding under the notes has been converted into common stock. At our option, at any time on or after March 30, 2002, the debentures may be prepaid by conversion of the principal into common stock at the conversion price of \$14.50, cash or any combination thereof and payment of any accrued interest as described above, provided that the average per share market value for the twenty consecutive trading days immediately preceding the date of prepayment equals or exceeds \$38.67 per share. The notes mature on March 29, 2004 and are payable in cash. The warrants grant the right to purchase one share of common stock at the exercise price of \$21.75 for each \$50.00 in face value of the convertible notes at any time before March 30, 2004. Approximately \$2,318,000 of the \$20,000,000 financing is allocated to the estimated fair value of the warrants and is included in additional paid in capital. This amount is amortized as a non-cash charge to interest expense over the life of the debentures. Debt issuance costs are included in other assets and are amortized to interest expense over the life of the debentures. In May 1999, we filed a registration statement for 2,096,333 shares of common stock issuable as follows: (1) 1,646,333 shares of common stock which may become issuable by reason of the conversion of the convertible debt, and accrued interest, (2) 400,000 shares which may become issuable upon the exercise of the warrants issued in the financing, and (3) 50,000 shares issued in connection with an asset purchase transaction. All shares have been reserved for issuance. In May 1999, the Securities and Exchange Commission declared this registration statement effective.

In 1999, we received notice of grants to support two research projects: (1) \$2,000,000 grant under the Advanced Technology Program of the National Institute for Standards and Technology ("NIST") to help support our development of an effective liver assist device prototype, which we expect to receive over the next two years commencing in December 1999; and (2) \$100,000 grant under the Small Business Innovation Research Program of the National Institutes of Health to support development of our vascular graft, which we have received \$50,000 in 1999 and expect to receive the next \$50,000 over the next three months. Both of these grants require that the federal government can access for its own purposes technology developed using the funding. A product developed based on the funding from the NIST grant must be manufactured substantially in the United States. In addition, we are subject to regular audit and reporting requirements.

In addition, we received notice from the Commonwealth of Massachusetts that we were selected to receive a workforce training grant for approximately \$162,000 to support employee training, which we have received \$40,000 in 1999 and expect to receive the remainder over the next twelve months.

In November of 1999, we entered into a \$5,000,000 term loan agreement with a commercial bank to finance the purchase of certain equipment, leasehold improvements and other items. Borrowings under the term loan are collateralized by a security interest in the items financed. The agreement provides repayment of the principal amount of the loan in 12 equal quarterly installments commencing December 29, 2000, with final payment due on September 30, 2003. The loan bears interest at a fluctuating rate per annum that is equal to the prime rate in effect from time to time, or we may elect that all or any portion of any term loan be made as a LIBOR loan with an interest period of one month, two months, three months or six months with the interest rate being equal to LIBOR plus an applicable margin (175 to 225 basis points). We are required to comply with certain covenants relating to our outstanding term loans, involving limitations on future indebtedness, dividends and investments; and to maintain certain financial covenants pertaining to liquidity, capital base, and debt service coverage (or, alternatively, maintaining a minimum unencumbered cash balance). Because we exercised our option to redeem all outstanding shares of Series C convertible preferred stock for cash subsequent to year end, we did not maintain compliance with the liquidity covenant as of December 31, 1999. The bank granted a waiver from this covenant. After raising additional capital subsequent to year end, we are now in compliance with all covenants. At December 31, 1999, we borrowed approximately \$4,728,000 against this term loan to finance certain research, manufacturing and office equipment and leasehold improvements. The weighted average interest rate paid during this period was 8.05%. This borrowing is collateralized by a security interest in the fixed assets financed.

On February 14, 2000, the Securities and Exchange Commission declared effective a shelf registration for the placement of up to 3,000,000 shares of common stock with an aggregate offering price not to exceed \$50,000,000. In February 2000, we completed a private placement of 788,925 shares of common stock at \$14.00 per share under this shelf registration yielding net proceeds of approximately \$10,800,000. Gruntal & Co. acted in an agency capacity for this placement. In March 2000, we completed a private placement of 300,000 shares of common stock at \$17.25 per share under this shelf registration yielding proceeds of approximately \$5,175,000. Additionally, from January 1 through March 29, 2000, we received approximately \$10,072,000 from the exercise of employee stock options.

#### Liquidity

Based upon our current plans, we believe that common stock issued subsequent to December 31, 1999, together with existing working capital and future funds from Novartis, including product and royalty revenue, will be sufficient to finance operations into 2001. However, this statement is forward-looking and changes may occur that would significantly decrease available cash before such time. Factors that may change our cash requirements include:

- o Delays in obtaining regulatory approvals of products in different countries, if needed, and subsequent timing of product launches;
- o Delays in commercial acceptance and reimbursement when product launches occur;
- o Changes in the progress of research and development programs; and
- o Changes in the resources devoted to outside research collaborations or projects, self-funded projects, proprietary manufacturing methods and advanced technologies.

Any of these events could adversely impact our capital resources, requiring us to raise additional funds. Management believes that additional funds may be available through equity or debt financing, strategic alliances with corporate partners, capital lease arrangements, or other sources of financing in the future. There can be no assurances that these funds will be available when required on terms acceptable to us, if at all. If adequate funds are not available when needed, we would need to delay, scale back or eliminate certain research and development programs or license to third parties certain products or technologies that we would otherwise undertake ourselves, resulting in a potential material adverse effect on our financial condition and results of operations.

#### Taxes

At December 31, 1999, we had federal net operating loss and tax credit carryforwards of approximately \$106,211,000 and \$3,305,000, and state net operating loss and tax credit carryforwards of approximately \$56,274,000 and \$1,476,000. These losses and tax credits are available to reduce federal and state taxable income and income taxes, respectively, in future years, if any. However, the realizability of deferred tax assets is not assured as it depends upon future taxable income. Accordingly, we have recorded a 100% valuation allowance against these assets. We are required to recognize all or a portion of net deferred tax assets, with corresponding increases to net income, when we believe, given the weight of all available evidence, that it is more likely than not that all or a portion of the benefits of net operating loss carryforwards and other credits will be realized. However, there can be no assurance that we will ever realize any future cash flows or benefits from these losses and tax credits. Ownership changes may result in future limitations on the utilization of net operating losses and research and development tax credit carryforwards.

#### Year 2000

We previously discussed the nature and progress of our plans to become Year 2000 ready. In late 1999, we completed our remediation and testing of systems. As a result of those planning and implementation efforts, we experienced no significant disruptions in mission critical information technology and non-information technology systems and believes those systems successfully responded to the Year 2000 date change. We are not aware of any material problems resulting from Year 2000 issues, either with our products, our internal systems, or the products and services of third parties. We will continue to monitor our mission critical computer applications and those of our suppliers and vendors throughout the year 2000 to ensure that any latent Year 2000 matters that may arise are addressed promptly.

#### Accounting Pronouncements

In June of 1998, the FASB issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities", which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities. We will adopt SFAS No. 133 as required by SFAS No. 137, "Deferral of the Effective Date of SFAS No. 133" in 2001. To date, we have not utilized derivative instruments or hedging activities and, therefore, the adoption of SFAS No. 133 is not expected to have a material impact on our financial position or results of operations.

SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101), was issued December 1999 and summarizes certain of the Staff's views in applying generally accepted accounting principles to revenue recognition in financial statements. The application of the guidance in SAB 101 will be required by the second quarter of 2000. The effects of applying this guidance, if any, will be reported as a cumulative effect adjustment resulting from a change in accounting principle. Our evaluation of SAB 101 is not yet complete.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ORGANOGENESIS INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements included in Item 8:

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Report of Independent Accountants

To the Board of Directors and Stockholders of Organogenesis Inc.:

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Organogenesis Inc. and its subsidiaries at December 31, 1999 and 1998, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 1999 in conformity with accounting principles generally accepted in the United States. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for the opinion expressed above.

PricewaterhouseCoopers LLP

Boston, Massachusetts  
March 27, 2000